

## **REMARKS**

### **Amendments to the Specification**

As indicated above, the specification is amended to properly describe trademarks, as appropriate.

### **Status of the Claims**

Claims 1-5, 7-8, 10, 12-13, 15-19, and 21-25 are pending in the present application. Claims 6, 9, 11, 14, and 20 were previously canceled. Claims 19 and 22 are withdrawn as being directed to non-elected inventions. Claims 1-5, 7-8, 10, 12-13, 16-17, and 21 are amended. Claims 23-25 are new. Support for the new claims and the claim amendments is described herein below. The claims are amended without prejudice or disclaimer. The Examiner is respectfully requested to enter the amendment since the amended claims are in condition for allowance. No new matter is entered by way of this amendment. Reconsideration is respectfully requested.

#### *Claim Amendments*

Claim 1 is amended to specify that the second antigen comprises at least the N-terminal collagen-binding part of SEC which comprises the amino acid sequence of *amino acids 2-303* in SEQ ID NO: 22. Support for the newly added element is found throughout the application as originally filed including, *e.g.*, on page 18, lines 2-8, (as indicated by the line numbering), which states that the amino acids of SEQ ID NO: 22, in bold, originate from the vector, *i.e.*, amino acid residue 1 (L=Leu) and amino acid residues 304-307 (L=Leu, E=Glu, P=Pro, G=Gly).

Claim 1 is further amended to specify that the third antigen comprises at least the immunogenic fragment of Sc1C, which fragment comprises the amino acid sequence of *amino acids 2-233* in SEQ ID NO:27. Support for this element is found throughout the application as originally filed including, *e.g.*, on page 21, lines 26-38, which states that the amino acids of SEQ ID NO: 27, in bold, originate from the vector, *i.e.* amino acid residue numbers 1 (M=Met) and 234-237 (L=Leu, E=Glu, P=Pro, G=Gly).

Claim 2 is amended to specify "consist of" in lieu of "are comprised of" and for consistency with amended claim 1.

Claim 3 is amended to specify that the collagen binding part of SEC comprises the amino acid sequence of *amino acids 2-590* in SEQ ID NO: 20. Support for this element is found throughout the application as originally filed including, *e.g.*, on page 17, lines 2-9, (as indicated by the line numbering), which states that the amino acids of SEQ ID NO: 20, in bold, originate from the vector, *i.e.*, amino acid residue numbers 1 (M=Met) and 304-307 (L=Leu, E=Glu, P=Pro, G=Gly).

Claim 4 is amended to specify “consists of” in lieu of “is comprised of” and for consistency with amended claims 1 and 2.

Claim 5 is amended to specify that the FNZ protein comprises the amino acid sequence of SEQ ID NO:2 or an N-terminal fibronectin-binding part of FNZ comprising the amino acid sequence of *amino acids 4-309* in SEQ ID NO:13. Support for this element is found throughout the application as originally filed including, *e.g.*, on page 13, line 26 to page 14, line 17, which states that the first three amino acids (M=Met, A=Ala, S=Ser) and the last amino acid (G=Gly) of SEQ ID NO: 13 originate from the vector.

Claim 5 is further amended to specify that the isolated protein designated SFS comprises the amino acid sequence of SEQ ID NO: 3 or a part of SFS comprising the amino acid sequence of *amino acids 3-121* in SEQ ID NO: 10. Support for this element is found, *e.g.*, on page 12, line 30 to page 13, line 3, which states that the amino acids of SEQ ID NO: 10, in bold, originate from the vector, *i.e.*, amino acid residue numbers 1 (M=Met) and 122-125 (L=Leu, E=Glu, P=Pro, G=Gly).

Claims 7, 8, 10, 12, 13, 16-17, and 21 are amended to specify “immunizing composition” in lieu of “vaccine”, (claims 13 and 16-17), or in lieu of “vaccine composition”, (claims 7, 8, 10, 12, and 21). Claim 12 is further amended to specify “for immunizing” in lieu of “for protecting.” Claims 16-17, as amended, are directed to a method for “immunizing.” Claims 16 and 17 are further amended to cancel the phrase “suitably horses”, (claim 16), “prophylactic”, (claim 16), “protecting”, (claim 16), and “subcutaneously or intranasally”, (claim 17).

The replacement of “vaccine composition” by “immunizing composition” is supported by the terms “immunize” and “immunization” as frequently used in the present application, for instance, in Examples 6, 8, 10, 11, 12, and 14-17. Further it is understood that “immunize” has

the generally recognized meaning of provoking an immune response, *i.e.* to raise antibodies.

#### *New Claims*

New claim 23 specifies that the immunizing composition reduces the severity of *S. equi* infection in non-human mammals. New claim 23 is supported, *inter alia*, in Examples 10 and 11, which describes that the vaccinated animals had fewer bacteria in their noses, in addition to a higher survival rate; and Example 16, which describes that the control group lost more weight than the groups that were given antigen.

New claim 24 specifies that the non-human mammals comprise horses. Support for this element is found *e.g.*, in original claim 16.

New claim 25 specifies that the horse is inoculated subcutaneously or intranasally. Support for this element is found, *e.g.*, in original claim 17.

#### **Statement of the Interview**

Applicants and Applicants' representative thank the Examiner for extending the courtesy of an interview on November 2, 2009. Applicants' representative noted that the URLs in the present application are not embedded hyperlinks since the symbols "< >" and http:// are not included with the URLs. The Examiner agreed to withdraw the objection.

#### **Objections to the Specification**

The Examiner objects to the specification for allegedly containing embedded hyperlinks and/or other form of browser-executable code on pages 14 and 19-20 of the instant application, *see Office Action*, page 2. Applicants note that the specification contains URLs, but the URLs are not embedded hyperlinks, *i.e.*, placed between the symbols "< >" and http:// followed by a URL address, *see MPEP* § 608.01. Accordingly, Applicants believe that it is not necessary to cancel the URLs. In addition, the Examiner indicated on November 2, 2009, that the objection would be withdrawn, *see above*.

The Examiner further objects to the present application for failing to properly indicate trademarks, *see Office Action*, page 3. As noted above, the instant application is amended to properly identify trademarks. Accordingly, withdrawal of the objection is respectfully requested.

### **Claim Objections**

Claims 2 and 4 are objected to under 37 C.F.R. § 1.75(c), as allegedly in improper dependent form for failing to further limit the subject matter of a previous claim, *see Office Action*, page 3.

In an effort to expedite prosecution, claims 2 and 4 are amended. In particular, claim 2 is amended to specify the phrase “consists of” in reference to the antigens described in claim 1. As amended, claim 4 specifies that the that third antigen “consists of” SCL C1 comprising the amino acid sequence of amino acids 2-233 in SEQ ID NO: 27.

In view of these amendments, claims 2 and 4 further limit claim 1. Accordingly, Applicants believe the rejection is overcome and respectfully request withdrawal.

### **Issues Under 35 U.S.C. § 112, First Paragraph**

#### *Written Description*

Claims 7-8, 10, 12-13, 16-18, and 21 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement, *see Office Action*, pages 4-5. Applicants respectfully traverse.

Specifically, the Examiner states that the present application lacks any description of a composition or method that elicits protective immunity. According to the Examiner, the claimed compositions induced an antibody response. However, the Examiner alleges that none of the claimed compositions was capable of preventing infection. Instead, the Examiner believes that the bacterial load and weight loss was merely reduced.

The instant claims are amended in an effort to expedite prosecution. As amended, composition claims 7, 8, 10, and 21 are directed to an immunizing composition, *i.e.*, a composition that induces an antibody response. Further, claims 12-13, 16-18, and 21 as amended, are directed to methods of preparing an immunizing composition (claims 12-13) or are directed to methods for immunizing or therapeutically treating non-human mammals (claim 16), or immunizing horses (claims 17-18). Accordingly, the amended claims are directed to subject

matter, which the Examiner states is supported by the present application. Accordingly, Applicants believe the rejection is overcome and respectfully request withdrawal.

*Enablement*

Claims 7-8, 10, 12-13, 16-18, and 21 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement, *see Office Action*, pages 5-7. Applicants respectfully traverse.

Specifically, the Examiner states that the present application is enabled for therapeutic compositions and methods for therapeutic treatment of *S. equi*. However, according to the Examiner, the present application does not reasonably provide enablement for vaccines or methods of prophylaxis against *S. equi*. The Examiner indicates that the compositions induced an antibody response. However, the Examiner states that none of the claimed compositions was capable of preventing infection. According to the Examiner, the claimed compositions reduced bacterial load and weight loss.

As noted above, claims 7-8, 10, and 21 are directed to immunizing compositions rather than vaccine compositions. In addition, the claims are not directed to the prevention or prophylaxis of *S. equi* infection, but to methods of immunizing or therapeutically treating *S. equi* infection or immunizing horses against *S. equi* infection. Accordingly, as amended, the claims encompass subject matter, which the Examiner indicates is enabled. Based upon the foregoing, Applicants believe the rejection is overcome and respectfully request withdrawal.

**Issues Under 35 U.S.C. § 112, First Paragraph**

Claims 1-5, 7-8, 10, 12-13, 15-18, and 21 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention, *see Office Action*, pages 7-8. Applicants respectfully traverse.

*Bases for the rejections*

Specifically, the Examiner states that claims 1, 2, and 4 are vague because SEQ ID NO: 22 must be a fragment of SEQ ID NO: 4, and SEQ ID NO: 27 must be a fragment of SEQ ID NO: 23. However, according to the Examiner, SEQ ID NO: 22 is not a fragment of SEQ ID NO: 4, and SEQ ID NO: 27 is not a fragment of SEQ ID NO: 23. The Examiner states that SEQ ID

NO: 27 includes amino acids that are not found in SEQ ID NO: 23. Therefore, according to the Examiner, SEQ ID NO: 27 is not a fragment of SEQ ID NO: 23.

The Examiner further states that claim 3 is vague because SEQ ID NO: 20 must be a fragment of SEQ ID NO: 4. However, according to the Examiner, examination of this sequence reveals that SEQ ID NO: 20 is not a fragment of SEQ ID NO: 4.

In addition, the Examiner states that claim 5 is vague because SEQ ID NO: 13 must be a fragment of SEQ ID NO: 2 and SEQ ID NO: 10 must be a fragment of SEQ ID NO: 3. However, examination of the sequences reveals that SEQ ID NO: 13 is not a fragment of SEQ ID NO: 2, and SEQ ID NO: 10 is not a fragment of SEQ ID NO: 3.

The Examiner also states that the term "suitably" renders claim 16 indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

*Applicants' response*

As noted above, claim 1 is amended to specify that the second antigen comprises at least the N-terminal collagen-binding part of SEC which comprises the amino acid sequence of *amino acids 2-303* in SEQ ID NO: 22. Accordingly, this amino acid sequence does not encompass the amino acid residues that are part of a cloning vector. Applicants further note that amino acids 2-203 of SEQ ID NO: 22 correspond to amino acids 27-238 of SEQ ID NO: 4. Accordingly, as amended, the amino acid sequence corresponding to amino acids 2-203 of SEQ ID NO: 22 is a fragment of SEQ ID NO: 4.

Claim 1 is further amended to specify that the third antigen comprises at least the immunogenic fragment of Sc1C, which fragment comprises the amino acid sequence of *amino acids 2-233* in SEQ ID NO: 27. Accordingly, this amino acid sequence does not encompass the amino acid residues that are part of a cloning vector. Applicants note that amino acids 2-233 of SEQ ID NO: 27 correspond to amino acids 38-269 in SEQ ID NO: 23. Accordingly, as amended, the amino acid sequence corresponding to amino acids 2-233 of SEQ ID NO: 27 is a fragment of SEQ ID NO: 23.

Claim 3 is amended to specify that the collagen binding part of SEC comprises the amino acid sequence of *amino acids 2-590* in SEQ ID NO: 20. Accordingly, claim 3 does not encompass the amino acid residues that are part of a cloning vector. Applicants note that amino

acids 2-590 correspond to amino acids 27-615 in SEQ ID NO: 4. Accordingly, as amended, the amino acid sequence corresponding to amino acids 2-590 in SEQ ID NO: 20 is a fragment of SEQ ID NO: 4.

Claim 5 is amended to specify that the FNZ protein comprises the amino acid sequence of SEQ ID NO:2 or an N-terminal fibronectin-binding part of FNZ comprising the amino acid sequence of *amino acids 4-309* in SEQ ID NO:13. Accordingly, this amino acid sequence does not encompass the amino acid residues that are part of a cloning vector. Applicants note that amino acids 4-309 correspond to amino acids 32-337 in SEQ ID NO: 2. Accordingly, as amended, the amino acid sequence corresponding to amino acids 4-309 in SEQ ID NO: 13 is a fragment of SEQ ID NO: 2.

Claim 5 is further amended to specify that the isolated protein designated SFS comprises the amino acid sequence of SEQ ID NO: 3 or a part of SFS comprising the amino acid sequence of *amino acids 3-121* in SEQ ID NO: 10. Accordingly, SEQ ID NO: 10 of claim 5 does not encompass amino acid residues that are part of a cloning vector. Applicants note that amino acids 3-121 correspond to amino acids 253-371 in SEQ ID NO: 3. Accordingly, as amended, the amino acid sequence corresponding to amino acids 3-121 in SEQ ID NO: 10 is a fragment of SEQ ID NO: 3.

Claim 16 is amended to cancel the term "suitably." Accordingly, this aspect of the rejection is moot.

In view of the foregoing, Applicants believe the rejections under 35 U.S.C. § 112, second paragraph, are overcome. Accordingly, withdrawal of the rejections is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, Applicants believe that the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact L. Parker, Reg. No. 46,046, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

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